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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/662,784	09/15/2000	Malcolm L. Gefter	IMI-044DV3CN	3152

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LAHIVE & COCKFIELD
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BOSTON, MA 02109

EXAMINER

TURNER, SHARON L

ART UNIT	PAPER NUMBER
1647	(C)

DATE MAILED: 05/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/662,784	GEFTER ET AL.
	Examiner	Art Unit
	Sharon L. Turner	1647

-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 03 February 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 95-110 is/are pending in the application.
- 4a) Of the above claim(s) 97-100 and 105-110 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 95,96 and 101-104 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) 95-110 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

Response to Amendment

1. The amendment filed 2-3-03 has been entered into the record and has been fully considered.
2. The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.
3. As a result of applicants amendment, all rejections not reiterated herein have been withdrawn by the examiner.

Election/Restriction

4. Applicant's election with traverse of Group I, therapeutic compositions to the extent of SEQ ID NO:6, claims 95-96 and 101-104 in Paper No. 12 is acknowledged. The traversal is on the ground(s) that the groups do not differ from each other but are similar in structure function and search and would not place undue burden upon the Examiner. This is not found persuasive because the different SEQ ID Nos define differences in structural constraints in particular with respect to epitopes and therefore are capable of different effects and usage. Because the searches are different each from the other the searches are not co-extensive and a search for a single member would not reveal all pertinent art to the other members.

The requirement is still deemed proper and is therefore made FINAL.

5. Claims 97-100 and 105-110 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 12.

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6. This application contains claims 97-100 and 105-110 drawn to an invention nonelected with traverse in Paper No. 12. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 95-96 and 101-103 stand rejected under 35 U.S.C. 102(a) as being anticipated by Littler et al., J. of Virol., 64(2):714-722, Feb. 1990 as evidenced by Harlow & Lane Cold Spring Harbor Labs, 1988, pp. 427, lines 15-17.

Littler et al., teach identification, cloning and expression of the Major Capsid Protein gene of HHV-6. The MCP protein residues 354-360 share 100% identity with instant SEQ ID NO:6 residues 103-109 which define an epitope of at least 6 amino acids. The recombinantly produced peptides were electroeluted and inoculated three times i.p. with 10 ug of protein and then once i.v. with 2 ug protein. The proteins produced antibodies reactive with HHV-6 samples and the peptide was detected from serum antibodies from infected patients. The composition comprises a mixture as more than a single peptide is included in the composition. As the peptides meet the structural limitations of the claims and are administered to animals producing an immunogen specific response, the reference teachings inherently anticipate a therapeutic

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composition comprising the peptide. The peptide compositions are the same and thus necessarily provide for those characteristics of a therapeutic composition as claimed.

Similarly as the isolated peptides are the same as claimed, they necessarily provide for the properties of claim 102. Applicants argue that the peptides used for producing antibodies in Littler did not include a peptide consisting of residues 354-360 of MCP and thus fail to teach an epitope. Applicants further argue that epitopes involve at least 7 residues as in Linvingstone.

Applicants arguments have been fully considered but are not persuasive.

Applicants claims are not limited to "consisting of terminology" and the claims are directed to peptide compositions and peptides that are not required to be administered. The Littler peptides are structurally the same as instant claims and thus the properties of the same peptides as claimed are inherently provided. In particular Harlow & Lane teach contrary to Livingstone, i.e., that epitopes may be of only 4 or 5 amino acids, see in particular p. 427, lines 15-17. Thus the Littler peptides are consistent with the structural limitations of the claims and thus inherently provide all characteristics absent factual evidence to the contrary.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claim 104 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Littler et al., J. of Virol., 64(2):714-722 in view of Hirschmann et al., US Patent No. 3,846,399 Nov. 5, 1974 as evidenced by Harlow & Lane Cold Spring Harbor Labs, 1988, pp. 427, lines 15-17.

Littler et al., teach as set forth above.

However, Littler et al., do not teach synthesis of the isolated polypeptide of claim 101 produced via chemical synthesis.

Hirschmann et al., teach a process for controlled stepwise chemical synthesis of peptides, see in particular Abstract, claims 1-9. The process provides the advantage of producing chemically pure polypeptides without the need for further purification, see in particular col. 2, lines 20-30, col. 8, lines 64-68.

Thus, it would have been prima facie obvious to the person of ordinary skill in the art at the time the invention was made to use the process of chemical synthesis as taught by Hirschmann to produce the peptides of cat allergen. One of skill in the art

would have expected success given the high skill in the art of chemically synthesizing amino acid peptides, the similarity of peptides produced recombinantly and chemically and the ability to stimulate antibodies with such peptides without the requirement of further purification from cell culture. The purity would ensure proper antigenicity as recognized by the reference teachings. Thus, the cumulative reference teachings render the invention obvious to one skilled in the art.

Applicants argue as set forth above that the Littler reference does not teach the invention.

Applicant's arguments have been fully considered but are not persuasive. Contrary to Livingstone, Harlow & Lane teach epitopes of only 4-5 amino acids and therefore the reference teachings render obvious the broadest reasonable interpretation of the claims.

Status of Claims

No claims are allowed.

CONCLUSION

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (703) 308-0056. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 6:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (703) 308-4623.

Sharon L. Turner, Ph.D.
May 7, 2003

Gary d. Kunz
GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600